

REMARKS

Specification

The specification was objected to because it contained a hyperlink. Applicant submits that by way of this amendment, the hyperlink located on page 8 of the specification has been deleted. The specification now refers to the journal publication upon which the hyperlink was based, and therefore, no new matter has been added by way of this amendment.

Claim Objections

Claim 26 was objected to because "*Bacillus thuringiensis*" was not italicized. In addition, the claim was drawn to a "method" while being dependent from claim 1, which is drawn to a locus.

Applicant submits that by way of this amendment, claim 26 is now drawn to a locus. Additionally by way of this amendment, the term "*Bacillus thuringiensis*" has been italicized in claim 26.

Claim Rejections – 35 USC §112, Second Paragraph

Claims 12 and 24 were rejected as being indefinite. Claim 12 was rejected because it was not clear what was meant by the phrase, "the first and second insecticidal toxin has a different mode of action to the second insecticidal toxin." The phrase "and second" in claim 12 has been deleted by way of this amendment. Applicant submits that claim 12 now particularly points out and distinctly claims the subject matter regarded as the invention.

Claim 24 was rejected because it recited a product trade name. Applicant submits that the term "Bollgard®" is defined in the specification on page 13, lines 1-6, wherein Bollgard® cotton plants produce at least the insecticidal toxin Cry1Ac. See MPEP 608.01(v):

However, if the product to which the trademark refers is set forth in such language that its identity is clear, the examiners are authorized to permit the use of the trademark if it is distinguished from common descriptive nouns by capitalization. If the trademark has a fixed and definite meaning, it constitutes sufficient identification unless some physical or chemical characteristic of the article or material is involved in the invention. In that event, as also in those cases where the trademark has no fixed and definite meaning, identification by scientific or other explanatory language is necessary. *In re Gebauer-Fuelnegg*, 121 F.2d 505, 50 USPQ 125 (CCPA 1941).

Applicant further submits that the trade name Bollgard® can be used in the claim because the meaning of the term has been adequately defined in the specification, and the term imparts a specific limitation to the claim. Applicant respectfully submits that claim 24 particularly points out and distinctly claims the subject matter regarded as the invention.

Claim Rejections – 35 USC §102(b)

Claims 1-4, 10-12, 15, 16, and 20 were rejected as being anticipated by Roush (*Phil. Trans. R. Soc. Lond. B*. 1998; 353:1777-1786). Claims 1 and 20 are independent. Claims 2-4, 10-12, 15, and 16 depend from claim 1. Claims 2 and 10 are cancelled by way of this amendment.

The Examiner alleges that Roush anticipates the claimed invention because Roush allegedly provides a method of controlling insects by providing a locus in which plant pests feed comprising a first region of plants expressing a first insecticidal toxin and a second region of plants expressing a second insecticidal toxin. Applicant respectfully disagrees. Roush actually teaches that there are three methods of deploying toxins: (i) individually but simultaneously, i.e. as a mosaic; (ii) sequentially; and (iii) pyramided. Roush goes on to state that sequential deployment is better than mosaic deployment and uses that statement as the basis for ignoring mosaics as an effective toxin deployment strategy. In effect, Roush teaches away from mosaics and sequentially in favor of pyramiding. Applicant respectfully submits that the subject matter of the claimed invention, i.e. the locus of claim 1 and method of claim 20, represents a fourth method of toxin deployment. Applicant respectfully submits that the Examiner has erred by assuming that mosaics anticipate the claimed invention. See for instance page 4 line 6-7, "This differs from the present invention which does not include mosaics." In contrast to Roush, which teaches away from using mosaics in a region, the present invention provides a locus comprising two regions, each comprising plants producing different insecticidal toxins, which is an effective tool in insect resistance management capable of controlling recessive or dominant resistance traits better than using a refuge.

Further regarding Roush, the author teaches that "a refuge is still necessary" (see page 1780, column 2). For transgenic crops, a refuge is the designation of a percentage of the cropped area as non-transgenic. Refuges are used in combination with a high dose of insecticidal agent, as currently mandated by some regulatory authorities, and serve to maintain a population of susceptible insects. This theory operates on the premise that resistance mechanisms observed in pests are due to recessive genes, and that if a refuge is maintained, then dominant susceptible genes will dilute any recessive resistance genes in the overall population. However, in instances where a resistance gene is dominant, or at least not recessive, the refuge concept falls apart. In essence, the use of refuges removes the pesticidal constraints on the pest population, and serves as a mechanism for producing a population of pesticide-resistant pests. Because of refuges, resistant pests which the farmer is trying to control in the field and which survive the pesticidal effects of feeding on the transgenic crop, are not killed. See page 3, lines 9-23 of the specification. The object of the present invention is to provide a locus at which pests feed comprising at least two regions which are capable of controlling recessive or dominant resistance traits better than using a refuge. See, for example, page 5, lines 9-10 of the specification. In order to clarify the scope of that which the Applicant regards as his invention, claims 1 and 20 have been amended to reflect that the locus is capable of controlling recessive or dominant resistance traits better than using a refuge.

Further regarding Roush, the Examiner alleges that Roush teaches that first and second toxins have different modes of action and different binding sites. Without conceding the propriety of the Examiner's opinion, Applicant respectfully submits that this does not rectify the deficiencies noted above, i.e. that what is taught by Roush still requires a refuge, which is in contrast to the claimed invention.

Yet further regarding Roush, the Examiner alleges that Roush teaches that one of the mechanisms for deployment of toxins is simultaneous distribution within a field or different fields. Without conceding the propriety of the Examiner's opinion, Applicant respectfully submits that this does not rectify the deficiencies noted above, i.e. that what is taught by Roush still requires a refuge, which is in contrast to the claimed invention.

Still further regarding Roush, the Examiner alleges that Roush specifically teaches that cotton plants possess different toxins. Without conceding the propriety of the Examiner's opinion, Applicant

respectfully submits that this does not rectify the deficiencies noted above, i.e. that what is taught by Roush still requires a refuge, which is in contrast to the claimed invention.

Applicant respectfully submits that by way of this amendment, Roush does not anticipate the claimed invention.

Claim Rejections – 35 USC §103(a)

Claims 5-9 and 17-19 were rejected as being unpatentable over Roush *supra*. Claims 5-9 and 17-19 depend from claim 1, now amended to recite the limitation that the locus is capable of controlling recessive or dominant resistance traits better than using a refuge.

The Examiner admits that Roush does not specifically teach seeding a second region within a mile or adjacent or around the perimeter of the first or alternating strips within the first. The Examiner further admits that Roush does not specifically teach a percentage of each toxin present in each locus. Furthermore, the Examiner admits that Roush depicts a refuge area of less than 5% within loci comprising two-toxin plants. Additionally, the Examiner admits that Roush provides the recommendation of Australia is that at least 20% of cotton and maize should be non-transgenic, i.e. a refuge. The Examiner submits that one would have been motivated to vary the percentage of toxin present at each of the two loci with the percentage of the amount of refugia provided to delay the onset of insect resistant to the toxins.

Applicant respectfully submits that the claim as amended provides a locus which is capable of controlling recessive or dominant resistance **better than using a refuge** (emphasis added). Applicant submits that the amount of refugia required with the present invention is zero. Applicant further submits that the prior art either (i) teaches that at least some refuge is required (see page 1780, column 2 of Roush *supra*), or (ii) is silent on the necessity of a refuge. Applicant further respectfully submits that neither Driver et al., Schnepf et al., nor English et al., taken together or separately, overcome the deficiency identified in Roush.

Summary

Independent claim 1, dependent claims 14-16, and independent claim 20 have been amended to recite the limitation that the second region comprises plants which produce at least a vegetative insecticidal protein (VIP) from *Bacillus thuringiensis*. Support for these amendments can be found in the specification on page 10, lines 23-24.

Independent claims 1 and 20 have been amended to recite the limitation that the locus is capable of controlling recessive or dominant resistance traits better than using a refuge. Support for these amendments can be found in the specification on page 5, lines 9-10.

In light of the above amendments and remarks, it is respectfully submitted that the present application is in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Examiner has had an opportunity to review the above remarks, the Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Office Action.

Respectfully submitted,

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